



UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/291,227	04/13/99	HAYEK	M IAM467PA

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KILLWORTH GOTTMAN HAGAN & SCHAEFF LLP
ONE DAYTON CENTRE
ONE SOUTH MAIN STREET SUITE 500
DAYTON OH 45402-2023

EXAMINER	
FAULKNER, D	
ART UNIT	PAPER NUMBER

1617

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DATE MAILED: 06/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/291,227

Applicant(s)

Hayek

Examiner

Faulkner, D.

Group Art Unit
1617



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

D. Faulkner

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicant refers to a “crude” protein. However, the specification does not describe what this limitation encompasses. The applicant can overcome this rejection by deleting this term. Applicant is enable for those proteins particularly disclosed in the specification. The determination of additional proteins useful in the claimed process would require undue experimentation by one of ordinary skill in the art.
2. Claims 1-3 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cats and dogs, does not reasonably provide enablement for all companion animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The applicant can overcome this rejection by limiting the language to the terms that applicant is enabled for. Applicant is enable for those species particularly disclosed in the specification. See ex. P. 1 lines 7-10 therein. The determination of additional species for which the claimed processes would be useful would require undue experimentation by one of ordinary skill in the art.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 and 12-16 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant refers to a method of enhancing immune response and improving overall health. The claims are indefinite as to conditions present in a host which are determinative of "overall health".

5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant refers to the initials IgG, clarification is needed by putting in the words that the applicant intends to encompass, such as immunoglobulin.

Claims 13 and 15 are objected to under 37 CAR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that the "intended use" for a composition in a particular host will not further limit claims drawn to compositions. See e.g. In re Hack 114 USPQ 161.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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7. Claims 1-5, 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by ^{Cerveny et al.} ~~Kim et al.~~
~~at, Lutein Uptake by Blood and Leukocytes in the dog, AN 1998:203976~~ ²⁰³³⁵⁴ or Kim et al, ~~or Kim et al.~~
~~at, Modulation of cell mediated immunity by dietary lutein in dogs AN 1998:203976~~ see abstracts enclosed

Kim describes a method of stimulating cell mediated and humoral immunity in dogs.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6-8, 10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim, et al, AN 1998:203976, ^{or Cerveny et al. AN 1998:203354.}

Kim et al. teaches the administration of dietary lutein, in the amounts of between 0-20 mg, to

^{See also Cerveny et al.}
dogs. [^]He teaches that administration of a dietary lutein composition increased the amount of

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lutein concentrations in the blood stream of dogs in a dose-dependent manner. He also teaches that the administration of lutein was effective enhancing cell mediated immune response in dogs.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the process of enhancing the immune system through lutein administration, as taught by Kim et al, who teaches such administration, within applicants effective ranges. The motivation is that the process is functionally the same using the same component.

10. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jyonouchi et al, Immunomodulating actions of carotenoid: AN 1994:321921 ~~further~~ in view of Anon, Ailment Specific dietary supplements, AN 97:19144.

Jyonouchi et al describes Immunomodulating actions of carotenoid including lutein for humoral immune responses.

Anon et al describes the ailment specific dietary supplements with lutein in food products used for building stress immunity.

It would have been obvious to one of ordinary skill in the art to use the imunomodulation actions of lutein, as demonstrated by Jyonouchi et al and the supplement forms of Anon in the administration of lutein for companion animals.

The motivation for combining the references is that they are equivalent compounds which are being administered for the same reason, building immunity.

11. It is appreciated that all of the upper amounts of administration for lutein are not explicitly disclosed by the references. However it would have been obvious to the artisan to optimize

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amounts in order to achieve effective results. Furthermore, while certain companion animals are Jyonouchi and Anon, i.e. mice and humans, the fact that each reference discloses that the same characteristics of lutein functioning in immune system enhancement demonstrates that the average artisan would expect lutein to have the same effect in any warm blooded animal.

12. Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biobusiness abstract 97:19144, Anon.

The abstract teaches that compositions comprising lutein are known in the art. The optimization of amounts of agents to be employed is considered within the skill of the artisan. Further, the "intended use" of a composition e.g. to improve immune response in specified animals, is not considered to further limit claims drawn to compositions. See e.g. In re Hack 114, USPQ 161.

It would have been obvious to one of ordinary skill in the art to utilize the lutein supplements of Anon in order to meet the composition as claimed by applicant. The motivation for using the supplement form is that such compositions are demonstrated in the prior art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Faulkner whose telephone number is (703) 305-4043. The examiner can normally be reached on Monday-Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Don Adams, can be reached on (703) 305-4043. The fax phone number for the organization where this application or proceeding is assigned is (703) 703-305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. Faulkner

M. May
PRIMARY EXAMINER
GROUP 1600